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ANNALS OF ONCOLOGY DRIVING INNOVATION IN ONCOLOGY

SPECIAL ARTICLE

ESMO Global Consortium Study on the availability, out-of-pocket costs, and accessibility of cancer medicines: 2023 update

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Background: The availability and affordability of safe, effective cancer therapies are core requirements for effective cancer control. Global disparities exist in access, however, yielding unequal cancer outcomes. The goal of this study was to provide updated data regarding the formulary availability, out-of-pocket costs, and accessibility of cancer medicines in countries across the full spectrum of economic development areas.

Methods: This study was conducted through an online survey based on a previously validated methodology. It evaluated the formulary availability, out of pocket costs, and actual accessibility of essential generic cancer medication commonly used for a wide range of cancers, including those on the 22nd WHO Model List of Essential Medicines (EML), and cancer medications used in eight high-incidence cancers. A total of 853 field reporters from 170 countries were invited to participate. The collected data were collated and peer-reviewed on the ESMO website, with final adjustments made accordingly.

Results: Data were collected by 317 reporters and 231 peer reviewers across 126 countries. The study revealed that patients in most high-income countries can access cancer medications without significant out-of-pocket expenditure, including novel treatments with high ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) scores. Conversely, in lower-middle and low-income countries, 40% of traditional chemotherapy agents deemed essential in the WHO EML are only available at full cost to patients.

Conclusions: This dataset provides a new and updated 'Global Reference' to enhance accountability for inequalities in access and availability of cancer medicines and to identify challenges and shortcomings to drive public health policies and positively impact national cancer control planning.

Key words: cancer medicines, ESMO-MCBS, WHO Model List of Essential Medicines, Universal Health Care, accessibility and affordability

INTRODUCTION

Cancer represents a public health pandemic of global proportion, with an estimate of 29.9 million new cancer cases globally by 2040.[1] The global toll of incidence and mortality of cancer weighs heavily on transitioning economies, where health systems are challenged by the steeper increase of the cancer burden, in addition to historical local health challenges, including endemic infectious diseases, with constrained health resources to develop the capacity to face the rising number of cases and deaths.

The European Society for Medical Oncology (ESMO) is committed to promoting access to affordable, high-value, quality cancer medicines as a prerequisite for effective cancer control. ESMO is committed to assuring timely and optimal treatment of patients with cancer because the availability of cancer medications directly affects the daily practice of clinicians and their ability to treat cancer patients.[2,3]

A common denominator affecting the ability to formulate, implement, monitor, revise, and readjust cancer

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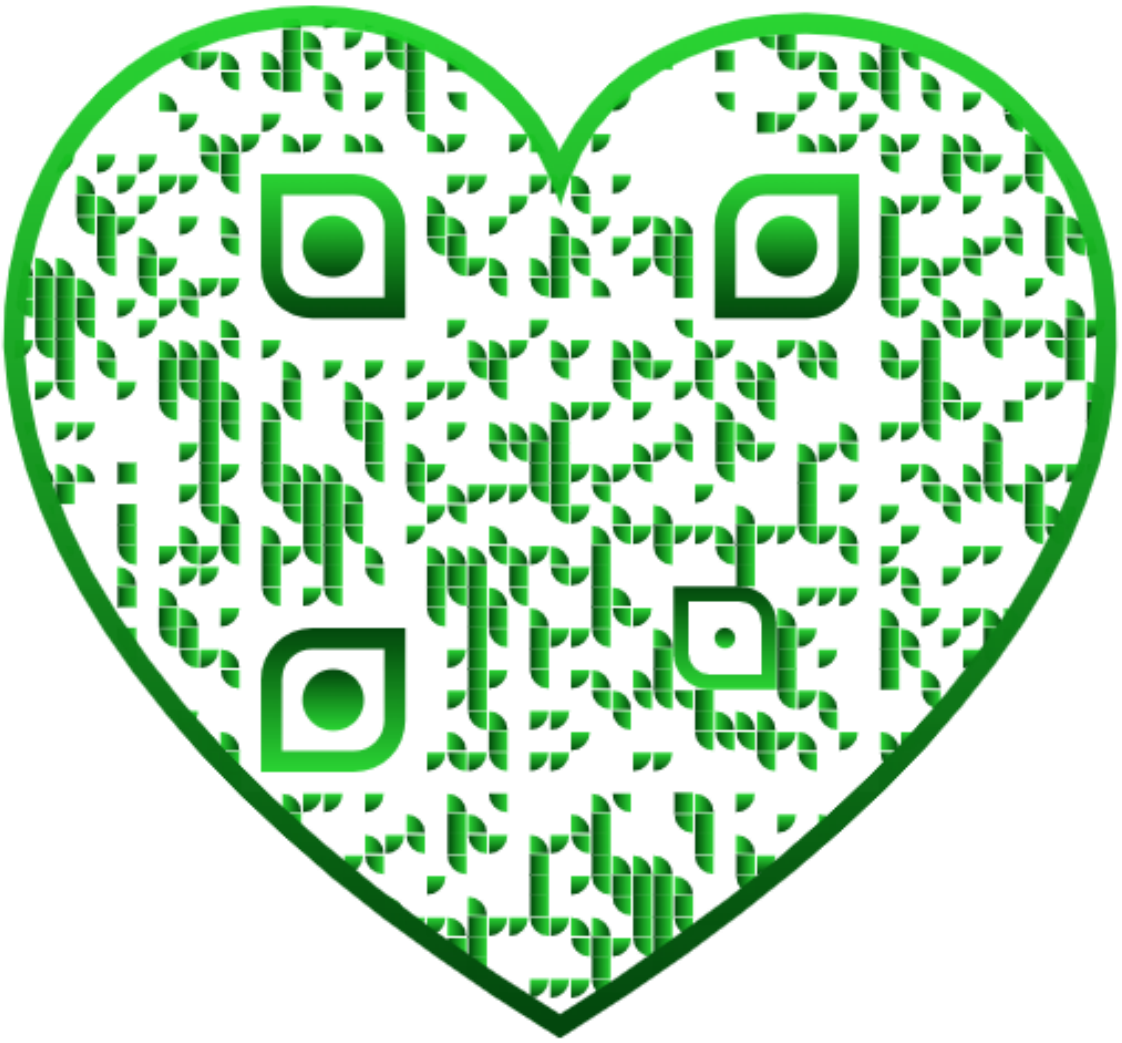

strategies of access to care is the lack of a global reference for access to cancer medicines that is regularly updated and can be used to base, track, and monitor the relevant cancer policies as implemented, or to be implemented. In 2016[4] and 2017,[5] ESMO provided data on the global status of access to cancer medicines, displaying the levels of access to cancer care based on national reimbursement policies for cancer interventions across countries of various income levels in multiple world regions. The data were alarming and showed that many patients are at risk of incurring financial hardship due to the out-of-pocket cost of basic, essential cancer treatments, especially in lower-middle- and low-income countries. In these countries, a third of the medicines on the 19th edition of the WHO's Model List of Essential Medicines (WHO EML) were available only at full out-of-pocket cost for patients; in low-income countries, less than half of these medicines were covered by some, or partial, governmental subsidies.

Based on this benchmark, ESMO launched a new survey to update the data on the global status of access to cancer medicines and evaluate the 5-year progress since its previous surveys. This is part of the work of the ESMO Cancer Medicines Committee to fulfil the ESMO vision to promote equitable access to clinically important cancer medicines.[2,3]

In this paper, we report the results of the second ESMO survey on the global accessibility and affordability of cancer medicines (ANMS-2). The aim of this study was to update the ESMO data regarding the availability of cancer medicines globally by (i) collecting data on formulary availability of licensed cancer medicines (at system-level), patient 'out-of-pocket' cost for the medication, and availability of medication for patients with a valid prescription (patient-level impact), (ii) the impact of the country's level of economic development on these parameters, and (iii) comparing them with the results of the 2016 and 2017 studies.

METHODS

Project development

The study was modelled on the previous ESMO Consortium Studies on the ANMS.[4,5] The study was developed by ESMO and the European Society of Oncology Pharmacy (ESOP) and implemented in collaboration with 44 national and regional oncology societies and networks (listed in the acknowledgements section).

Study format and data collection

The questionnaire-based survey tool was modelled on the previous ANMS[4,5] and was distributed using the Qualtrics survey platform. The survey questions are reported in Supplementary File S1, available at https://doi.org/10.1016/j.annonc.2024.12.005.

The survey consisted of three parts: (i) general questions regarding the country's health care system, (ii) questions regarding the formulary availability, out-of-pocket costs, and actual accessibility of essential cancer medication commonly used over a wide range of cancers, included on 22nd WHO EML,[6] and (iii) the same data relating to cancer medications used in eight common cancers [adjuvant and metastatic breast cancer, colorectal cancer, gastrointestinal stromal tumour (GIST), lung cancer, melanoma, renal and prostate cancer].

The list of cancer medications for each disease entity was derived from the previous ANMS studies and updated with new approvals by either the United States Food and Drug Administration (FDA) or the European Medicines Agency (EMA) as of May 2021. The list was then edited for relevance by the project leaders to include other medicines commonly used off-label.

ESMO and the collaborating partners sought to identify at least two field reporters, either oncologists or oncology pharmacists, through an iterative process for each country. The field reporters were derived from the ESMO membership, and national or approved representatives of the professional organisations collaborating in this project and were also drawn from the previous ANMS studies.

Field reporters were asked to indicate the following for each medication: whether it was permissible to prescribe the cancer medicine for the stated indication, the average proportion of the full retail price patients are obliged to pay out-of-pocket for the medication, and the actual accessibility of the medication for most patients in the country when prescribed.

Between May 2021 and March 2023, 611 field reporters from 163 countries were invited to participate. Repeated reminders were sent to non-responding invitees. Data submitted between 5 May 2021 and 15 June 2022 by the field reporters were tabulated and graphically presented in colour-coded tables (in the format used in the previous ESMO studies[4,5]) and then cross-checked.

When discrepancies were identified, if possible, a third reviewer from the same country was used as a tiebreaker. When there were more than two reviewers the majority opinion was used. In case of a major discrepancy in the response of two or more reviewers from the same country (i.e. in accessibility 'never/always' and in affordability 'full cost/free'), an intermediate grade was selected (i.e. half the time for accessibility and 25%-50% of the cost for affordability).

Following the analysis of the preliminary data (presented at the ESMO 2022 Congress),[7] 242 additional experts from 61 countries were identified and invited to complete the survey from 20 January 2023 to 4 March 2023 to obtain data from as many countries as possible. The data were added to the colour-coded tables of the preliminary data presented at ESMO 2022, and further analysis was conducted to cross-check data from multiple reporters from the same country.

The updated preliminary data were posted on the ESMO website for external validation from 28 July 2023 to 10 September 2023, to support the robustness of the information provided, to indicate discrepancies in the data, and to provide additional information on hitherto unreported countries. Invitations to review the data and submit any

corrections or amendments were sent to all members of the collaborating partner organisations, to reporters invited to complete the survey (both those who completed it and those who did not), and an open invitation was extended to all ESMO members.

Amendments were collated, cross-checked, and incorporated into the final results, which were presented at the ESMO 2023 Congress.[8]

The country data were stratified according to the level of each country's economic development based on the World Bank income grouping,[9] classifying them as high income (HICs), upper-middle income (UMICs), lower-middle income (LMICs), and low income (LICs) and presented alphabetically by country name.

For clarity of presentation and to highlight findings of inequity and impact, this report focuses on (i) medications included in the 22nd edition of the WHO EML and (ii) recently approved medications with a score $\geq$4 or A on the ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS)—corresponding to a substantial level of clinical benefit that are not included in the 22nd WHO EML.[10] Comparison to the previous studies of 2016-2017 is presented in the discussion.

The WHO EML includes medications the WHO deems necessary for a basic health care system to function effectively.[11] These medicines are considered essential because they address the most important health care needs and are considered cost-effective, safe, and readily available. The WHO EML is updated every other year to reflect current medical knowledge and changing health priorities and is a valuable reference tool for promoting access to essential medicines and improving health care outcomes globally. The medications included in the 22nd edition of the WHO EML for adult solid tumours largely consist of older chemotherapy and hormonal medicines with a relatively small number of new and expensive immune-mediated and targeted treatments, which include trastuzumab and its biosimilars for breast cancer, imatinib for GISTs, Philadelphia chromosome-positive acute lymphoblastic leukaemia, and chronic myeloid leukaemia, erlotinib, gefitinib, and afatinib for epidermal growth factor receptor (EGFR) gene mutated non-small-cell lung cancer, and pembrolizumab and nivolumab for metastatic melanoma.

The ESMO-MCBS is a standardised, validated tool for assessing the clinical benefit of cancer treatments. It provides a systematic and transparent approach to evaluate the magnitude of clinical benefit offered by new cancer therapies, including medicines, biologics, and supportive care interventions.[10,12] Using the ESMO-MCBS scores of A or B on a point scale of A, B, C for curative treatments, and 4 or 5 on a five-point scale for non-curative treatments, are regarded as indicating substantial benefit.[10,12]

RESULTS

Data collection and reporters

Responses to the surveys were submitted by 317 reporters from 121 countries. The respondents included 194 medical oncologists (61%), 59 pharmacists (20%), 53 clinical oncologists (radiation oncologists) who prescribe systemic cancer therapy (17%), and 7 government health officials with knowledge of medicine formulary (2%). Additional peer-review data were submitted by 231 reporters from 99 countries in the open consultation process, including 5 countries where data had not been previously reported. Data were eventually collected from 126 countries (Table 1 and Supplementary File S2, available at https://doi.org/10.1016/j.annonc.2024.12.005).

Chemotherapy and hormonal therapies included in the 22nd WHO EML

In HICs and UMICs, most of the chemotherapy and hormonal medicines included in the 22nd WHO EML are on the formulary. They are available to patients at no cost or on a subsidised basis (Figure 1A). In LMICs and LICs, limited accessibility was reported, and in many countries, patients incur full out-of-pocket costs even for generic essential cancer medications (Figure 1B). These gaps in access appeared prominent in Afghanistan, Burkina Faso, Bangladesh, Cambodia, Cameroon, Ghana, Haiti, Honduras, India, Lebanon, Madagascar, Nepal, Nigeria, Niger, Philippines, Rwanda, Zambia, and Zimbabwe.

Issues related to the accessibility of these medicines were reported to be substantially more prevalent in LMICs and LICs where accessibility is often unreliable and with non-continuous availability and unreliable procurement (Figures 2A and B). For example, this was particularly the case in El Salvador, Kenya, Somalia, and Venezuela.

New and expensive immune-modulating and targeted therapies included in the 22nd WHO EML

With few exceptions, in almost all HICs and most UMICs, trastuzumab (and its biosimilars) in breast cancer, and erlotinib, gefitinib, and afatinib in non-small-cell lung cancer, and nivolumab and pembrolizumab in melanoma were almost always available to patients at no cost or on a subsidised basis (Figure 3A). In LMICs and LICs, when available, however, these medications are generally provided only at full cost as an out-of-pocket expenditure for patients (Figure 3B).

There is a very substantial discrepancy in the accessibility of these immune-modulating and targeted therapies relative to HICs and UMICs versus LMICs and LICs (Figure 4A and B). This effect is slightly less prominent for imatinib than for other new biological medicines.

Approved new biologic and hormonal therapies not on the 22nd WHO EML, with ESMO-MCBS v1.1 score $\geq$4 (4 or 5) for advanced cancers or scored A in the curative disease setting

Among the spectrum of diseases evaluated in the survey, there were stark differences in the formulary availability, out-of-pocket cost, and accessibility for new biological and hormonal therapies not included in the 22nd WHO EML with high ESMO-MCBS scores. With very few notable exceptions (i.e. New Zealand, Latvia, and Chile), most of these

Table 1. Country and respondent demographics

WHO world region[a]	Total countries per region[b]	Countries that participated in the survey	Percent of countries surveyed in region	Total population (bil)[c]	Surveyed population (bil)	Percent of the surveyed population
African region	47	19	40%	1.192	0.835	70%
Eastern Mediterranean region	21	18	86%	0.775	0.761	98%
European region	54	48	89%	0.923	0.868	94%
Region of the Americas	35	20	57%	1.028	0.997	97%
South-East Asia region	11	7	64%	2.071	2.042	99%
Western Pacific region	28	14	50%	1.969	1.928	98%
Total	**196**	**126**	**64%**	**7.958**	**7.435**	**93%**

Bil, billions; WHO, World Health Organization.
[a]This includes Palestine (within the European Region) and Taiwan (in the Western Pacific Region).
[b]World Health Organization. Countries. 2024: https://www.who.int/countries
[c]Population data derived from: Worldometers. Population by country. 2024: https://www.worldometers.info/world-population/population-by-country.

medications were available with no out-of-pocket costs in most HICs and with a substantial reduction in out-of-pocket costs in a minority of HICs (Figure 5A). This contrasts with the situation in UMICs where these medications are on formulary, however, in most cases, only at full out-of-pocket costs (Figure 5A), and with the situation in LMICs and LICs in which these medications are often not available, and when they are available it is generally only at full cost (Figure 5B).

Full tabular reports

The complete tabular reports for widely used generic medications and the eight disease-related indications surveyed are presented in Supplementary File S3, available at https://doi.org/10.1016/j.annonc.2024.12.005.

DISCUSSION

In this paper we provided the updated 2023 ESMO dataset on the global status of access to cancer medicines. We show that patients from most HICs can usually access cancer medicines without incurring out-of-pocket expenditures, including high-value, novel cancer medicines with high ESMO-MCBS scores. This is in stark contrast to the situation in many LICs and LMICs, where even access to medicines on the WHO EML is limited, often with substantial out-of-pocket expenditure for patients. The results of this study can be instrumental to health authorities as they make policy decisions for national cancer control planning and access to cancer medicines, ensuring that strategies are data-driven and that health care delivery is impact-oriented, representing the current benchmark reference for access to cancer medicines.

Access to medicines on the WHO EML remains problematic in LMICs and LICs. This trend is magnified with the addition of new effective but expensive biological treatments that were more recently included in the WHO EML. Additionally, we report that novel cancer agents with the highest therapeutic potential are still very inaccessible to patients in all but HICs. These data are consistent with the 2021 survey of 83 countries by the WHO EML Cancer Medicines Working Group, which identified similar formulary deficiencies and a high risk of 'catastrophic expenditure' on cancer medicines in LICs and LMICs.[13,14]

Compared with the 2016 and 2017 ESMO data,[4,5] some progress has been demonstrated in access to chemotherapy and hormonal agents, particularly in some UMICs, where substantial improvement of access has been identified towards reimbursement and coverage of innovative, high-value medicines, such as in Argentina, Brazil, China, Kazakhstan, and Turkey.

Improvements in access to cancer therapies usually result from updates of cancer-specific, access-oriented health policies. We have previously detailed policy steps that can be undertaken to improve access particularly for new and expensive high-benefit agents.[4] Kazakhstan initiated a review of its cancer formulary and reimbursement programme in consultation with ESMO, using a structured analysis based on the WHO EML, ESMO Clinical Practice Guidelines, ESMO-MCBS, and an expert review.[15] This review led to the withdrawal of several low-value or non-evidence-based therapies and to the increase of the budget for cancer care to include all essential and highly effective medicines and treatment options.[15] Structured approaches to health technology assessment are becoming more common in developing economies and are now active in Brazil, Mexico, Thailand, India, Argentina, Turkey, Chile, Colombia, Peru, Vietnam, Egypt, Pakistan, Philippines, Kenya, and Nigeria.[16] Despite multiple policy initiatives, mainly through efforts of the WHO[17-21] and the United Nations (UN),[22,23] the updated dataset indicates that most of the inequities observed in the previous surveys[4,5] remain.

Utility of these data for individual countries

To formulate and inform cancer policies intended to improve cancer care, individual countries need to have a general sense, and detailed information on the contemporary status of access to cancer medicines. By mobilising the power of data-driven decision-making, individual countries can use the findings from this survey to improve access to

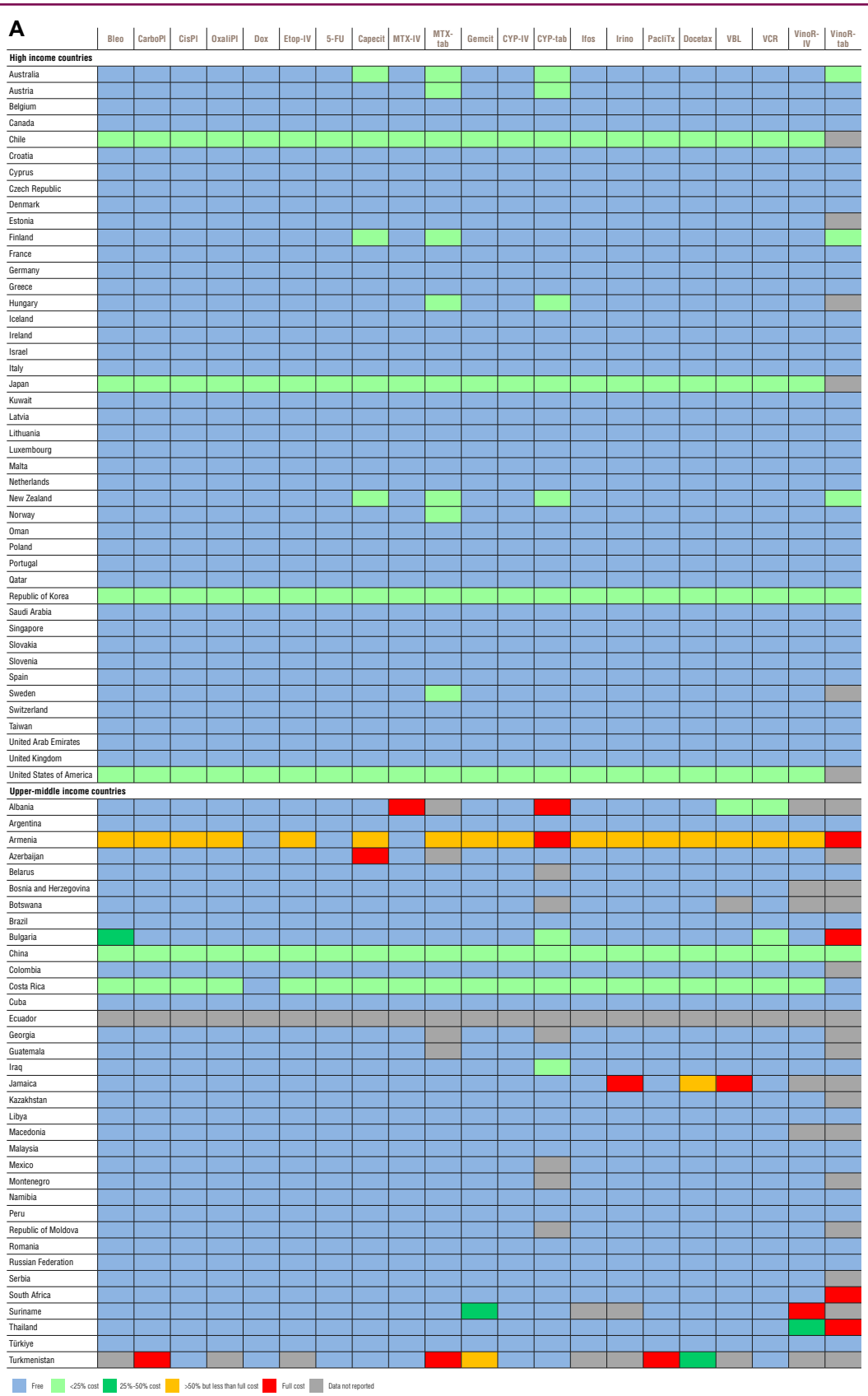

Figure 1. Examples of chemotherapy on the 22nd WHO EML—formulary availability and out-of-pocket costs. (A) High- and upper-middle-income countries. (B) Lower-middle- and low-income countries.

5-FU, 5-fluorouracil; Bleo, bleomycin; CarboPl, carboplatin; Capecit, capecitabine; CisPl, cisplatin; CYP-IV, cyclophosphamide intravenous; CYP-tab, cyclophosphamide tablets; Docetax, docetaxel; Dox, doxorubicin; Etop-IV, etoposide intravenous; Gemcit, gemcitabine; Ifos, ifosfamide; Irino, irinotecan; vinorelbine tablets; MTX-IV, methotrexate intravenous; MTX-tab, methotrexate tablets; OxaliPl, oxaliplatin; PacliTx, paclitaxel; VBL, vinblastine; VCR, vincristine; VinoR-IV, vinorelbine intravenous; VinoR-tab, vinorelbine tablets; WHO EML, World Health Organization Essential Medicines List.

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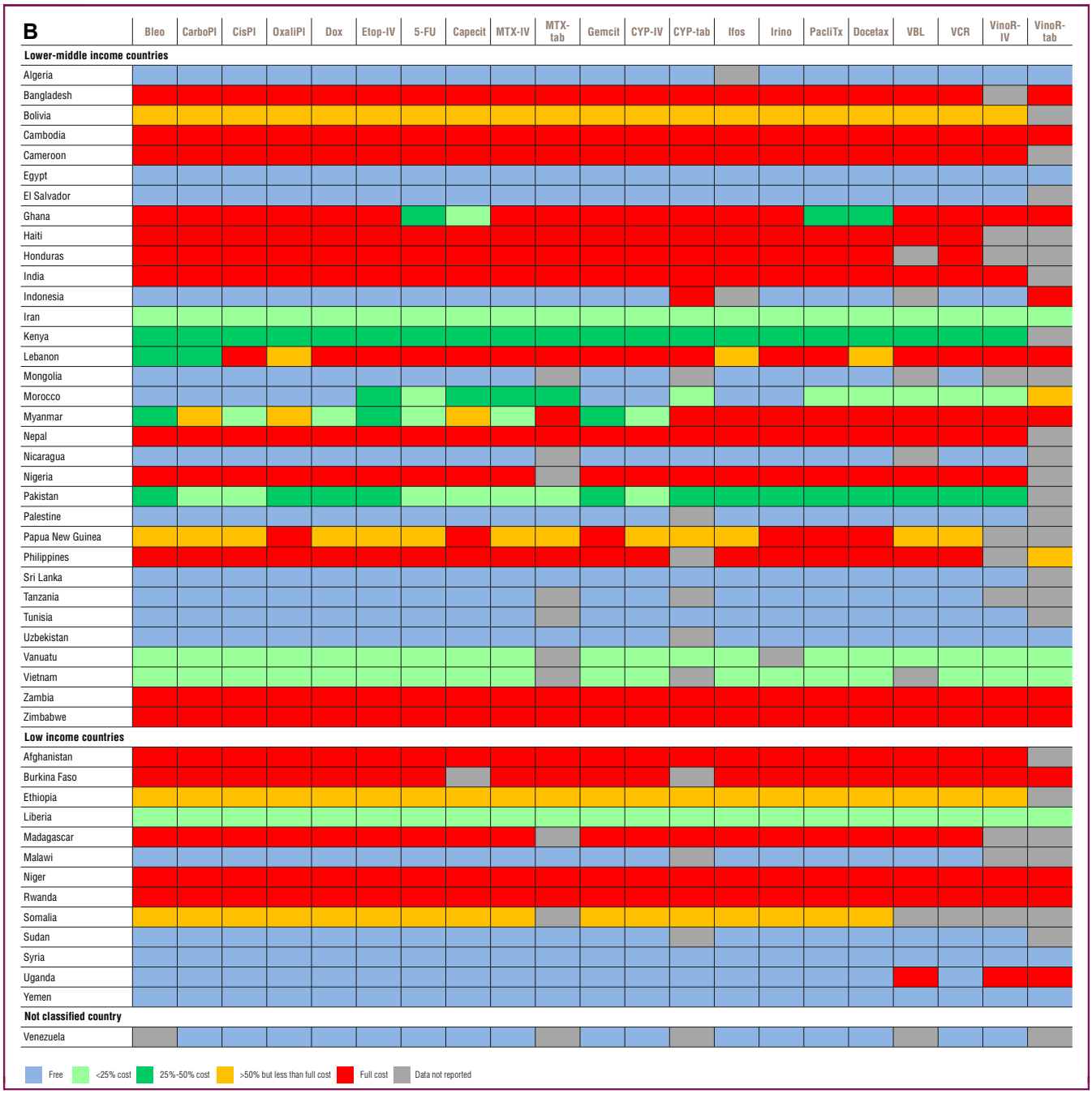

Figure 1. **Continued.**

cancer medicines. The ESMO dataset can serve as a valuable resource for identifying gaps in the accessibility and affordability of cancer medicines within a country's health care system and to design targeted interventions to enhance access to cancer care services. Additionally, governments can use these data to raise public awareness about the importance of equitable access to anticancer medicines and can mobilise public support for initiatives aimed at improving cancer care infrastructure and expanding access to essential medicines for all individuals affected by cancer.

Utility of these data for global organisations

This updated dataset can contribute to global monitoring frameworks, such as WHO's Global Health Observatory[24] and the World Health Report,[17] providing insights into global trends in anticancer medicine availability, accessibility, and affordability. These data are particularly relevant to the WHO Fair Pricing initiative, which addresses the cost of anticancer medication and its impact on patient care,[25,26] and to initiatives addressing the indications for compulsory licensing to make expensive medications affordable and available for patients with cancer.[27]

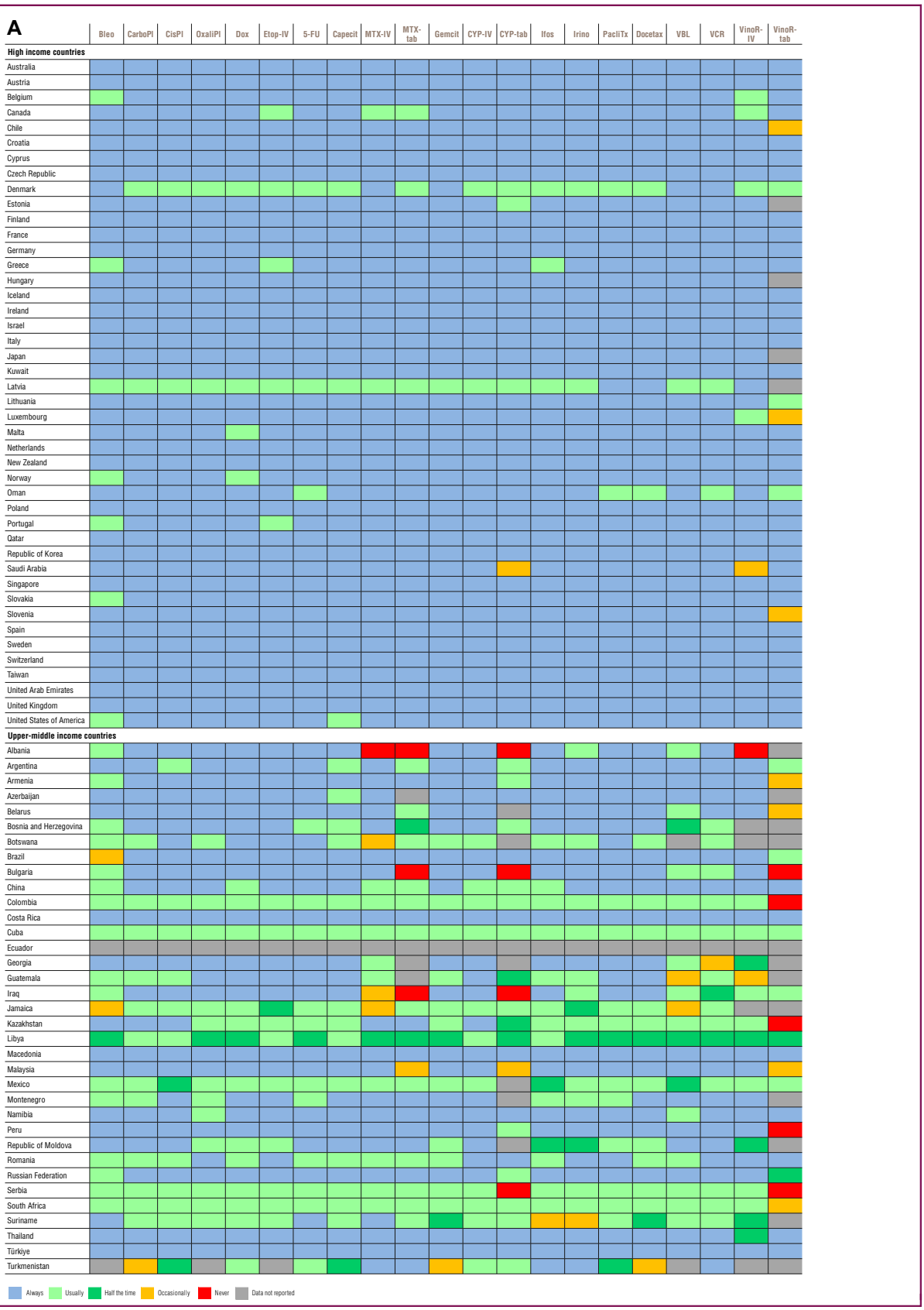

Figure 2. Examples of chemotherapy on the 22nd WHO EML—actual availability (accessibility with a valid prescription). (A) High- and upper-middle-income countries. (B) Lower-middle- and low-income countries.

5-FU, 5-fluorouracil; Bleo, bleomycin; CarboPl, carboplatin; Capecit, capecitabine; CisPl, cisplatin; CYP-IV, cyclophosphamide intravenous; CYP-tab, cyclophosphamide tablets; Docetax, docetaxel; Dox, doxorubicin; Etop-IV, etoposide intravenous; Gemcit, gemcitabine; Ifos, ifosfamide; Irino, irinotecan; vinorelbine tablets; MTX-IV, methotrexate intravenous; MTX-tab, methotrexate tablets; OxaliPl, oxaliplatin; PacliTx, paclitaxel; VBL, vinblastine; VCR, vincristine; VinoR-IV, vinorelbine intravenous; VinoR-tab, vinorelbine tablets; WHO EML, World Health Organization Essential Medicines List.

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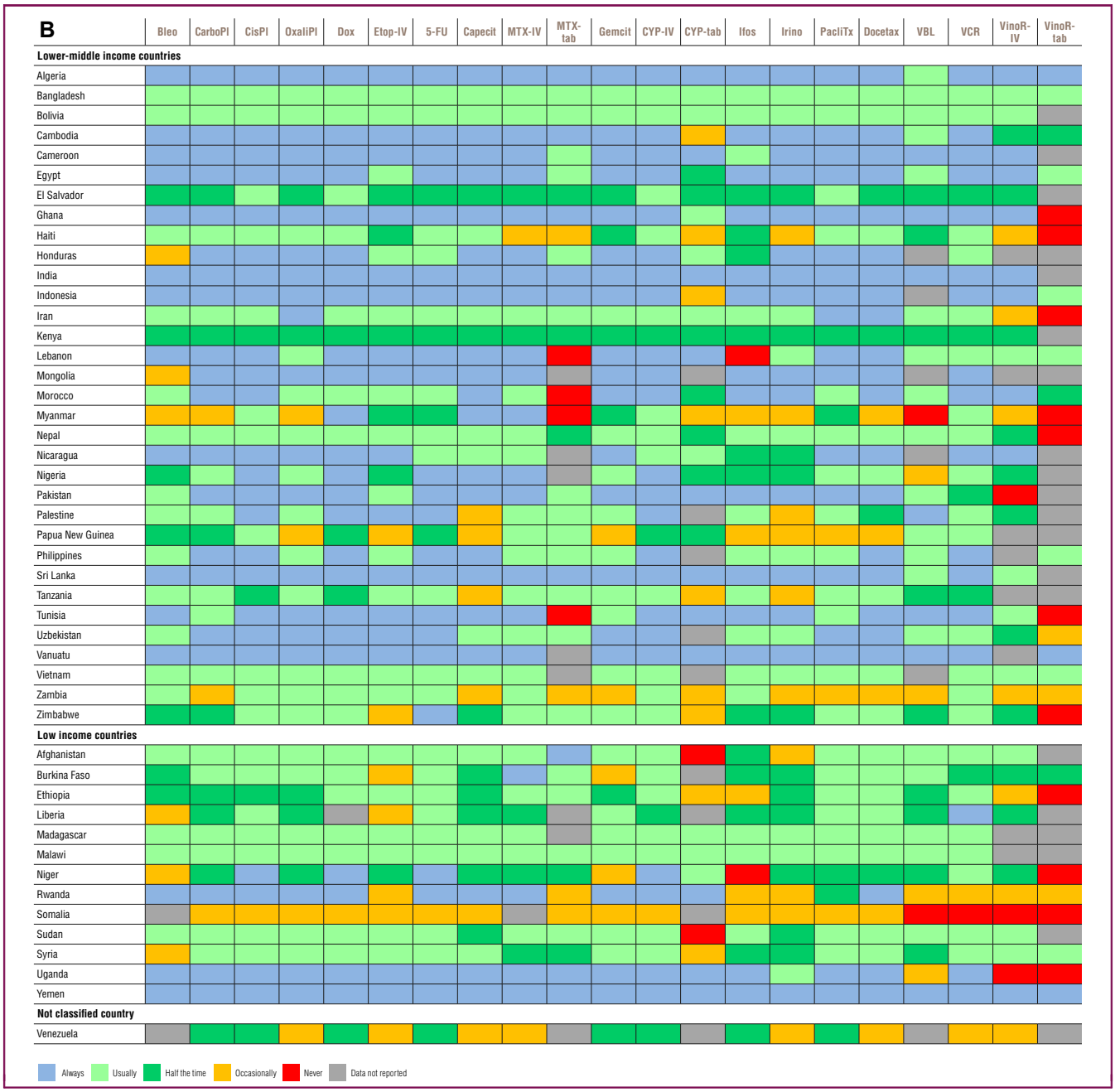

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International organisations can facilitate coordination among member states. For example, by sharing experiences, lessons learned, and best practices, countries can collectively identify innovative solutions to common problems and leverage each other's strengths and resources to improve cancer outcomes globally.

Finally, these data will also be of benefit to non-governmental organisations (NGOs) which are involved in improving access to affordable anticancer medicines in countries with developing economies, such as the Access to Medicine Foundation,[28] the Medicines Patent Pool,[29] and the recently initiated Access to Oncology Medicines project.[30]

Future plans

ESMO has highlighted that the WHO Model Lists of Essential Medicines and *In Vitro* Diagnostics Lists are key tools to help prioritise cancer medicines and technologies and has advocated for their alignment. One of the main barriers to access to precision oncology is the availability of a suitable targeted medicine and its companion biomolecular diagnostics, as reported in the ESMO study on the availability and accessibility of biomolecular technologies in oncology in Europe (BMT).[31]

ESMO is working to create an online mapping tool to visually show the data from this study (ANMS-2) and the BMT study. This virtual mapping tool will also allow the

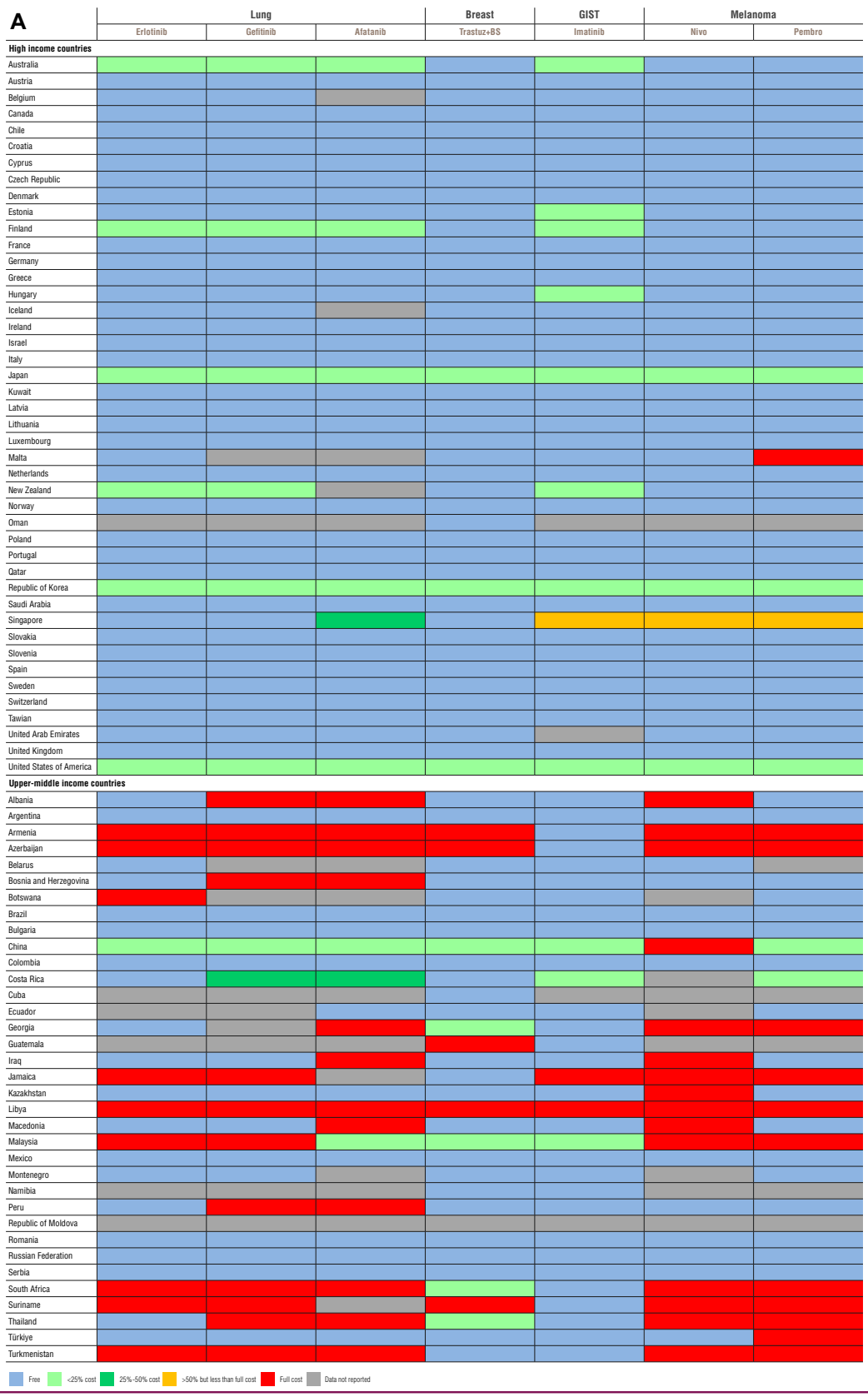

Figure 3. New and expensive immune-mediated and targeted therapies on the 22nd WHO EML - formulary availability and out-of-pocket costs. (A) High- and upper middle-income countries. (B) Lower-middle- and low-income countries.
GIST, gastrointestinal stromal tumour; Nivo, nivolumab; Pembro, pembrolizumab; Trastuz+BS, trastuzumab (and its quality-assured biosimilars); WHO EML, World Health Organization Essential Medicines List.

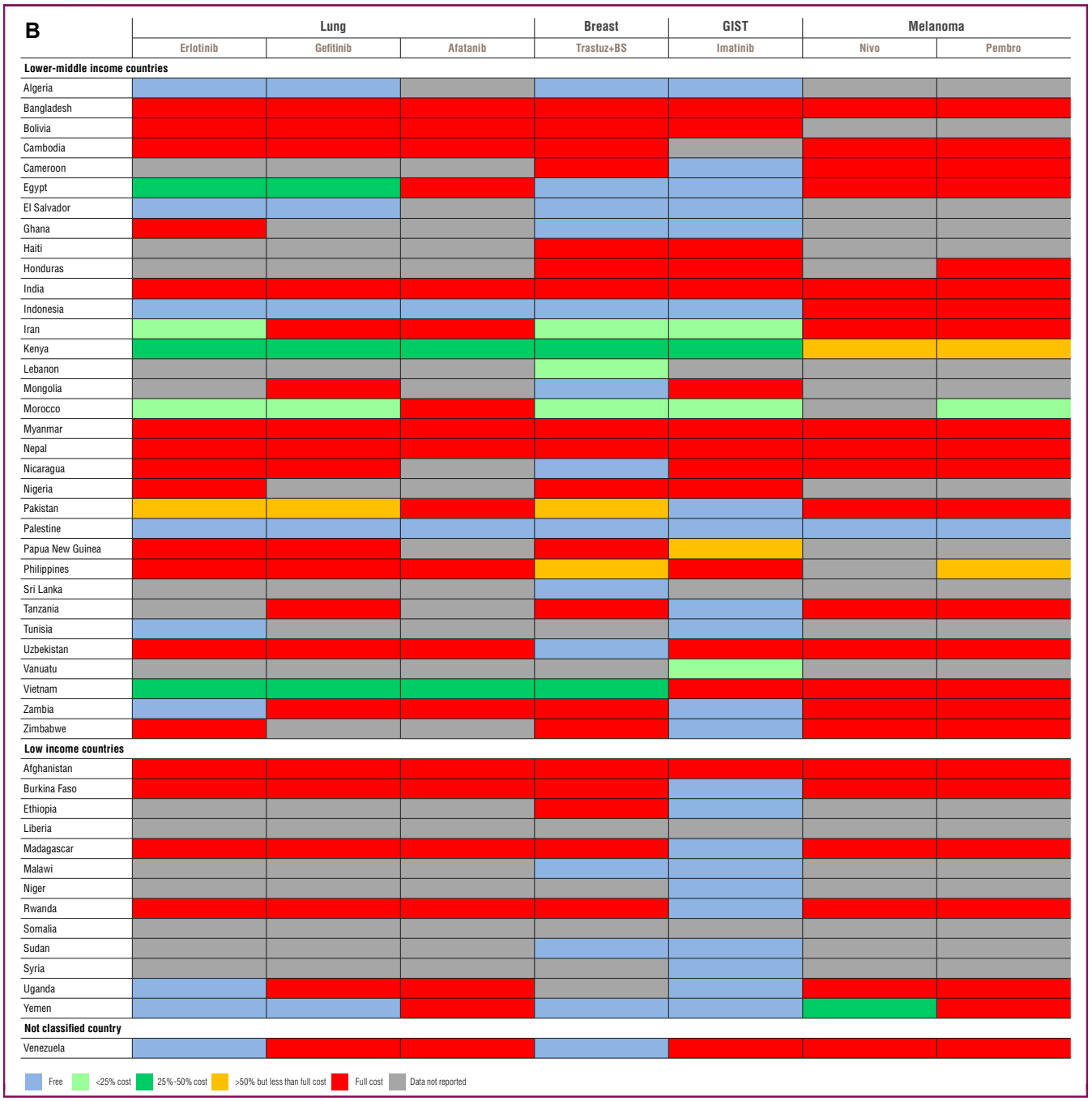

Figure 3. **Continued.**

comparison of data by year and the availability of a medicine with a related biomolecular technology. The mapping tool will also facilitate the use of the survey data for policy, advocacy, and research purposes, supporting the global cancer community's efforts towards achieving health-for-all and identifying the gaps that need to be addressed to improve access to cancer care for patients globally.

DISCLAIMERS

The information presented in this study represents a time-constrained 'snapshot' of the situation, as perceived and reported by the country reporters during the survey period, with the understanding that the data may change over time.

The data have been collected mainly from practicing clinicians and pharmacists working in the field rather than from state authorities or statutory bodies (except in exceptional cases where no country reporter was available). Reporters were asked to consult with regulatory authorities in circumstances in which they were unsure of an issue, such as a formulary issue or the cost of medicines to patients.

When submitted responses were incomplete, submitted data were entered, and items not addressed were marked as missing data.

The data's accuracy depends on the reporting accuracy of country reporters and their due diligence in verifying facts.

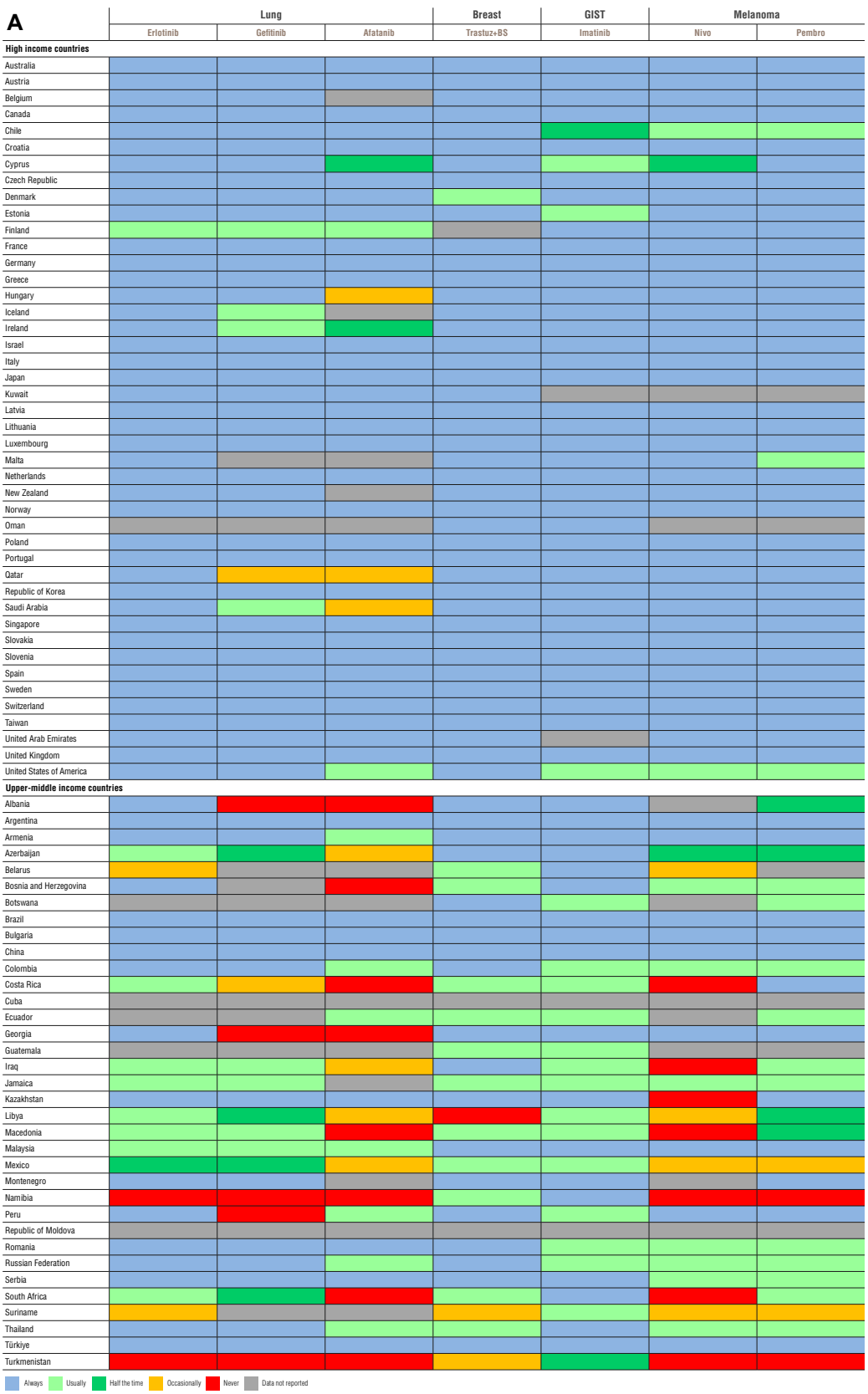

Figure 4. New and expensive immune-mediated and targeted therapies on the 22nd WHO EML - actual availability (accessibility with a valid prescription). (A) High and upper-middle-income countries. (B) Lower-middle and low-income countries.
GIST, gastrointestinal stromal tumour; Nivo, nivolumab; Pembro, pembrolizumab; Trastuz+BS, trastuzumab (and its quality-assured biosimilars); WHO EML, World Health Organization Essential Medicines List.

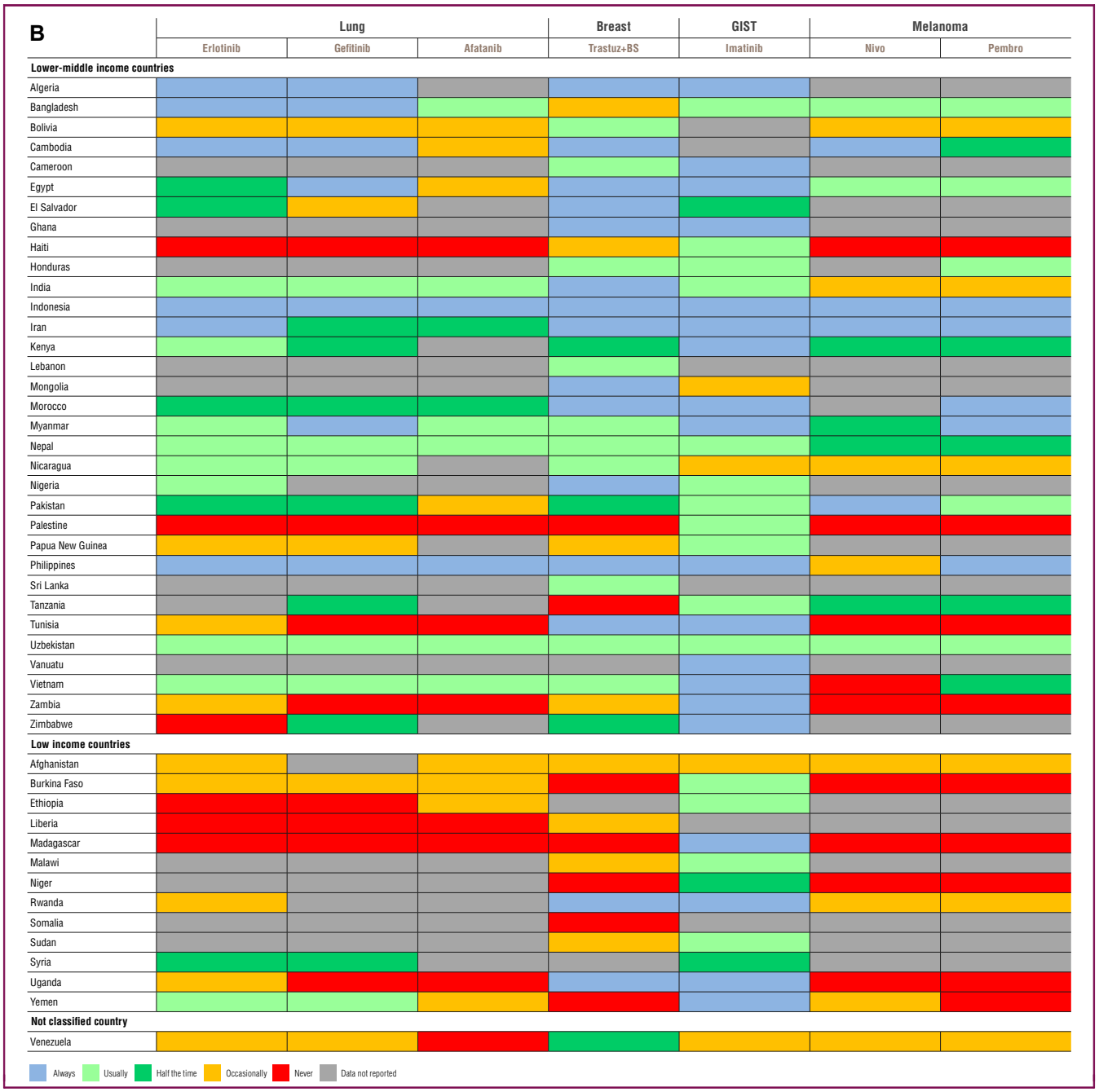

Figure 4. Continued.

Country reporters were nominated based on their recognised involvement in oncology practice, their participation in their national professional society, and, in many cases, their leadership positions in their country.

The methodology used in this study incorporates measures to minimise error by incorporating multiple reporters, cross-checking between reporter data, and an open peer review process of the data collected. Cross-checking between reporters was not possible in 35 countries where submissions were received by only one reporter and in 21 of these countries no peer review reports were submitted.

In some limited situations (such as availability of oral formulations of cyclophosphamide, etoposide or vinorelbine), difference in accessibility can be based on well-considered policies and is not necessarily to the patients' disadvantage.

CONCLUSION

This global study was framed within ESMO's '2025 vision' to enhance 'Accessible and Sustainable Cancer Care'.[2] This dataset provides a new and updated 'Global Reference' to enhance accountability for inequalities in access and availability of cancer medicines and to identify challenges and shortcomings to drive public health policies and positively impact national cancer control planning.

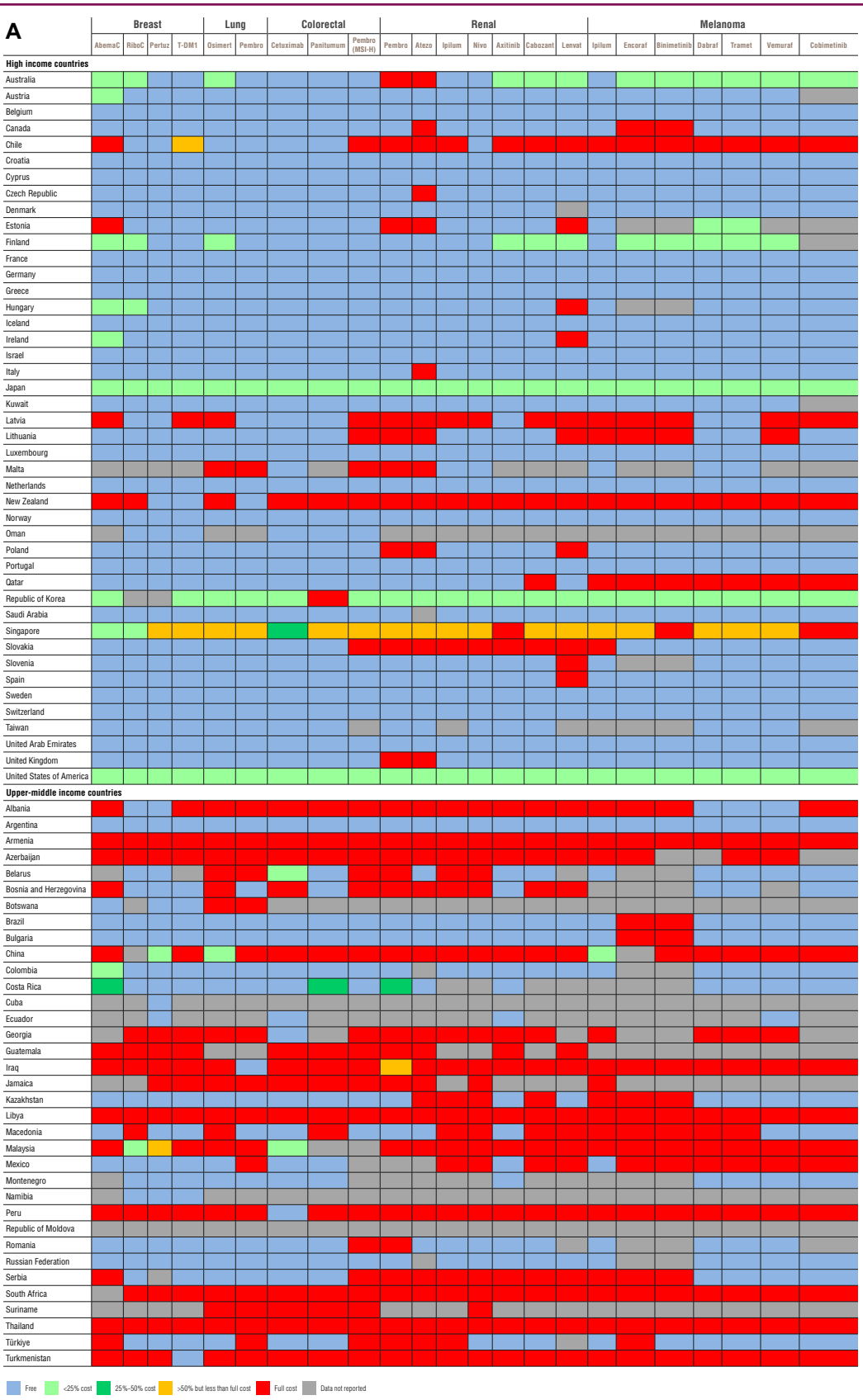

Figure 5. High-benefit biological and hormonal therapies not on the 22nd WHO EML - formulary availability and out-of-pocket costs. (A) High- and upper-middle income countries. (B) Lower-middle and low-income countries.
AbemaC, abemaciclib; Atezo, atezolizumab; Cabozant, cabozantinib; Dabraf, dabrafenib; Encoraf, encorafenib; Ipilum, ipilimumab; Lenvat, lenvatinib; Nivo, nivolumab; Osimert, osimertinib, Pembro, pembrolizumab; Pembro (MSI-H), pembrolizumab (for microsatellite instability-high metastatic colorectal cancer); Panitumum, panitumumab; Pertuz, pertuzumab; RiboC, ribociclib; Tramet, trametinib; T-DM1, trastuzumab emtansine; Vemuraf, vemurafenib; WHO EML, World Health Organization Essential Medicines List.

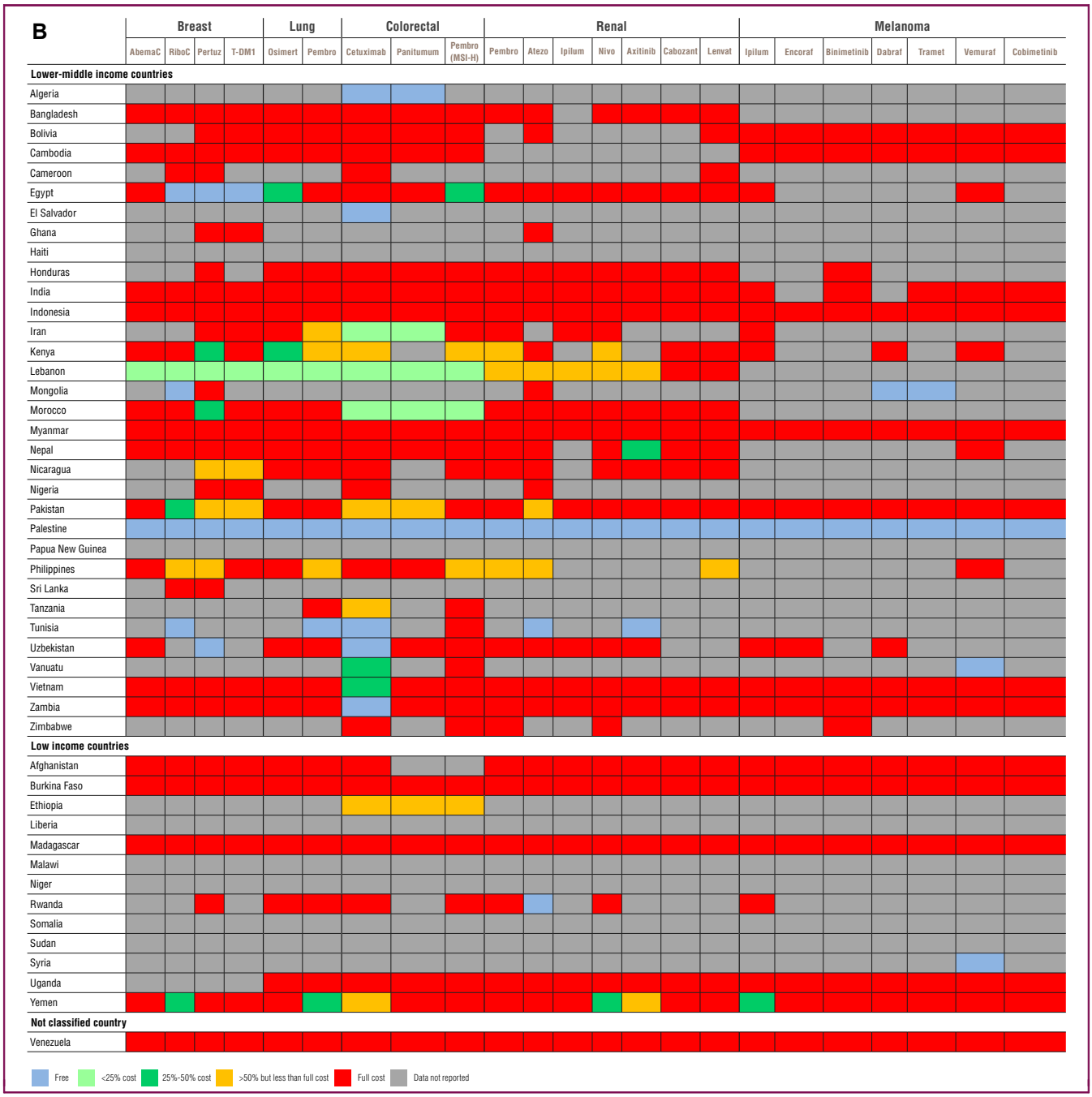

Figure 5. Continued.

Major inequities in access to cancer medicines still exist. Sadly, this is true not only for expensive innovative cancer medicines, but also for inexpensive essential cancer medicines. These inequities are determined by health system capacity, medication costs, financial investments in cancer control, and national income levels.

Despite focal areas of substantial improvement, the study indicates inadequate progress since the last published report 5 years ago. Governments and NGOs need to accelerate and redouble their actions if they are to achieve the Sustainable Development Goal of Universal Health Coverage by 2030 (target 3.8)—a goal they recommitted to in the second UN Political Declaration on Universal Health Coverage adopted in September 2023.[32]

ESMO will continue its efforts to support improving access to effective cancer interventions through its advocacy and work at the European level and its collaboration with WHO on global cancer projects aimed at making affordable cancer care available for all.

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